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No. 06-152

IN THE

Supreme Court of the United States

R & F PROPERTIES OF LAKE COUNTY, INC.,
F/K/A LEESBURG FAMILY MEDICINE,
Petitioner,

v.

UNITED STATES OF AMERICA *EX REL.* KARYN L. WALKER,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

MOTION FOR LEAVE TO FILE A BRIEF AS *AMICUS CURIAE* AND BRIEF OF *AMICUS CURIAE* PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA IN SUPPORT OF PETITIONER

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MOTION OF THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA TO FILE A BRIEF AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

The Pharmaceutical Research and Manufacturers of America hereby requests, pursuant to Rule 37.2 of the Rules of this Court, leave to file the accompanying brief as *amicus curiae* in support of petitioner. PhRMA obtained the consent of petitioner.

The issue presented in this petition significantly affects PhRMA's interests and those of its members. PhRMA is a trade association that brings together the shared interests of the country's leading pharmaceutical research and biotechnology companies to accomplish common goals. PhRMA's primary mission is to advocate for public policies that encourage the discovery of life-saving and life-enhancing new

medicines by pharmaceutical research and biotechnology companies. PhRMA thus has a substantial interest in ensuring that the legal standards governing the pharmaceutical industry are stable, predictable, and consistent with sound public policy.

The question presented by this case is whether persons who submit claims to the government based on objectively reasonable interpretations of ambiguous statutes or regulations can be liable for fraud under the civil False Claims Act. This issue is critically important to the nation's pharmaceutical manufacturers, which in the last five years have become a primary target of FCA suits based on alleged violations of ambiguous rules. These suits have resulted in numerous multi-million dollar settlements. In the absence of a clear and uniform rule that FCA liability cannot be based on a reasonable interpretation of an ambiguous statute or regulation, manufacturers will continue to face enormous pressure to settle these cases in order to avoid the risk of exposure to the FCA's severe financial penalties. PhRMA thus has a vital interest in the issue presented in this case and its views can assist the Court in deciding whether certiorari should be granted.

For the foregoing reasons, PhRMA's Motion for Leave to File a Brief as *amicus curiae* should be granted.

Respectfully submitted,

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TABLE OF CONTENTS

	Page
TABLE OF AUTHORITIES	ii
BRIEF OF *AMICUS CURIAE*	1
INTEREST OF THE *AMICUS CURIAE*	1
INTRODUCTION AND SUMMARY OF THE ARGUMENT	1
ARGUMENT	2
I. THE ISSUE RAISED BY THE PETITION IS EXCEEDINGLY IMPORTANT TO THE PHARMACEUTICAL INDUSTRY	2
A. Pharmaceutical Companies Have Become A Primary Target Of FCA Suits, Many Of Which Have Resulted In Enormous Settlements	2
B. FCA Suits Against Pharmaceutical Companies Are Often Based On The Alleged Violation Of Ambiguous Regulations	4
C. There Are Other Remedies Available To Ensure Compliance With Regulatory Requirements	14
II. THE DECISION BELOW IS WRONG, CREATES UNCERTAINTY, AND INCREASES THE INCENTIVE TO SETTLE MERITLESS FCA SUITS	16
CONCLUSION	20

TABLE OF AUTHORITIES

CASES Page

Nevada ex rel. Steinke v. *Merck & Co.*, 432 F. Supp. 2d 1082 (D. Nev. 2006) 11
Rehabilitation Ass'n of Va., Inc. v. *Kozlowski*, 42 F.3d 1444 (4th Cir. 1994) 6
United States v. *Southland Mgmt. Corp.*, 326 F.3d 669 (5th Cir. 2003) 17
Walker Process Equip., Inc. v. *Food Mach. & Chem. Corp.*, 382 U.S. 172 (1965) 17
Washington Legal Found. v. *Henney*, 128 F. Supp. 2d 11 (D.D.C 2000) 13

STATUTES AND REGULATIONS

31 U.S.C. §§ 3729-3733 1
38 U.S.C. § 8126 5
42 U.S.C. § 1396r-8 ..... 5, 8, 9
§ 256b(a)(1) 4
48 C.F.R. § 33.210 16
§ 52.233-1 16
Medicaid Program; Drug Rebate Agreement, 56 Fed. Reg. 7049 (Feb. 21, 1991) 9, 10, 11, 15
Citizen Petition Regulating the FDA's Policy on Promotion of Unapproved Drugs & Devices, 59 Fed. Reg. 59,820 (Nov. 18, 1994) 13
Medicaid Program; Payment for Covered Outpatient Drugs Under Drug Rebate Agreements with Mfrs., 60 Fed. Reg. 48,442 (Sept. 19, 1995) (to be codified at 42 C.F.R. pts. 441 & 447 6
Final Guidance on Industry-Supported Scientific & Educational Activity, 62 Fed. Reg. 64,074 (Dec. 3, 1997) 12

TABLE OF AUTHORITIES – continued

Page

Prescription Drug Advertising & Promotional Labeling; Development & Use of FDA Guidance Document, 62 Fed. Reg. 14,912 (Mar. 28, 1997) 13

Decision in *Washington Legal Found.* v. *Henney*, 65 Fed. Reg. 14,286 (Mar. 16, 2000) 12

LEGISLATIVE HISTORY

136 Cong. Rec. S12954 (daily ed. Sep. 12, 1990) .. 10

SCHOLARLY AUTHORITIES

Jonathan K. Henderson & Quintin Cassady, *Drug Deals in 2006: Cutting Edge Legal and Regulatory Issues in the Pharmaceutical Industry*, 15 Annals Health. L. 107 (2006) 2, 3, 17, 18

Marc J. Scheineson & Shannon Thyme Klinger, *Lessons from Expanded Government Enforcement Efforts Against Drug Companies*, 60 Food & Drug L.J. 1 (2005) 3, 17, 18

Correy E. Stephenson, *Health Care Whistleblower Suits Are on the Rise*, Law. Wkly. USA, Nov. 21, 2005 ..... 3, 4

OTHER AUTHORITIES

Pharmaceutical Pricing Agreement (Mar. 24, 2005) (on file with author) 5, 15

SmithKline Whistleblowers Get $42.3 Million, Pa. L. Wkly., Apr. 20, 1998 18

Centers for Medicare & Medicaid Servs., Dep't of Health & Human Servs., No. 14, Medicaid Drug Rebate Program Release (1994) 10

Centers for Medicare & Medicaid Servs., Dep't of Health & Human Servs., No. 28, Medicaid Drug Rebate Program Release (1997) 7

TABLE OF AUTHORITIES – continued

Page

Centers for Medicare & Medicaid Servs., Dep't of Health & Human Servs., No. 29, Medicaid Drug Rebate Program Release (1997) 7

Centers for Medicare & Medicaid Servs., Dep't of Health & Human Servs., No. 30, Medicaid Drug Rebate Program Release (1997) 7

The False Claims Act Legal Center, Top 20 Cases, *available at* http://www.taf.org/top20.htm 4

GAO, Report to Cong. Requestors, *Medicaid Drug Rebate Program: Inadequate Oversight Raises Concerns about Rebates Paid to States* (Feb. 4, 2005) 5, 6

Letter from Margaret M. Dotzel, Assoc. Comm'r for Policy, FDA, to Daniel J. Popeo and Richard A. Samp (Jan. 28, 2002), *available at* http://www.fda.gov/ohrms/dockets/dailys/02/Jan02/013002/01p-0250_pdn0001_01_vol2.pdf 12

Peter Keisler, Assistant Att'y Gen., Civil Division, U.S. Dep't of Justice, Remarks to the Taxpayers Against Fraud Education Fund Conference for Relators' Counsel, Washington, D.C. (Oct. 14, 2004) 3

Master Agreement Between The Sec'y of Veterans Affairs (Hereinafter Referred To As "The Sec'y") And The Mfr. Identified in Section VIII Of This Agreement (Hereinafter Referred To As "The Mfr.") (n.d) (on file with author) 5, 16

Office of the Inspector General, A-06-91-0092, *Medicaid Drug Rebates: The Health Care Financing Administration Needs to Provide Additional Guidance to Drug Manufacturers to Better Implement the Program* (Nov. 1992) 6

TABLE OF AUTHORITIES – continued

Page

Press Release, U.S. Dep't of Justice, Bayer Corporation and GlaxoSmithKline To Pay $344 Million To Resolve Allegations of Health Care Fraud Against State Programs (Apr. 16, 2003) (on file with author) 7, 9

Press Release, U.S. Dep't of Justice, Schering-Plough To Pay $345 Million To Resolve Criminal and Civil Liabilities for Illegal Marketing of Claritin (July 30, 2004) (on file with author) 7

Press Release, U.S. Dep't of Justice, AstraZeneca Pharmaceuticals LP Pleads Guilty To Healthcare Crime; Company Agrees To Pay $355 Million To Settle Charges (June 20, 2003) (on file with author) 7

Press Release, U.S. Dep't of Justice, King Pharmaceuticals To Pay U.S. $124 Million For Medicaid Rebate Underpayments & Overcharging For Drug Products (Nov. 1, 2005) (on file with author) 7

Press Release, U.S. Dep't of Justice, Drug Giant Pfizer & Two Subsidiaries To Pay $49 Million For Defrauding Drug Medicaid Rebate Program (Oct. 28, 2002) (on file with author) 8

Press Release, U.S. Dep't of Justice, Warner-Lambert To Pay $430 Million To Resolve Criminal & Civil Health Care Liability Relating To Off-Label Promotion (May 13, 2004) (on file with author) 14

BRIEF OF *AMICUS CURIAE*

The Pharmaceutical Research and Manufacturers of America respectfully submits this brief as *amicus curiae* in support of petitioner.[1]

INTEREST OF THE *AMICUS CURIAE*

The interest of the *amicus curiae* is set forth in the accompanying motion for leave to file this brief.

INTRODUCTION AND SUMMARY OF THE ARGUMENT

The issue raised by this case is whether an entity that is subject to complex regulatory requirements can be held liable for engaging in fraud under the civil False Claims Act ("FCA"), 31 U.S.C. §§ 3729-3733, when its actions are based on an objectively reasonable interpretation of an ambiguous statute or regulation. This issue is exceedingly important to the country's pharmaceutical manufacturers, which are subject to a host of extraordinarily complicated and often ambiguous statutes and regulations. The government has an array of tools at its disposal to clarify ambiguous statutory and regulatory requirements, as well as the power to require corrective actions by entities that acted on the basis of contrary but reasonable interpretations of those requirements. But in recent years, pharmaceutical companies have become a frequent target of *fraud* claims based on alleged violations of ambiguous statutes and regulations. In the absence of a clear and uniform rule that liability under the FCA – which predicates liability on the "knowing" submission of a false claim – cannot arise in such circumstances, many pharmaceutical companies face the Hobson's choice of agreeing to huge set-

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[1] Pursuant to Supreme Court Rule 37.6, *amicus* states that no person or entity other than *amicus*, its members, or its counsel made a monetary contribution to the preparation or submission of this brief. Further, no counsel for either party has authored this brief in whole or in part.

tlements or litigating and risking exposure to the FCA's potentially devastating financial penalties.

The decision below is wrong and contrary to decisions issued by other federal courts. It is fundamentally unfair to hold a company liable *for fraud* where the company acted pursuant to an objectively reasonable interpretation of an ambiguous statute or regulation. The varying positions taken by the courts of appeals create an unacceptable level of uncertainty, and this uncertainty increases the substantial incentives FCA plaintiffs have to pursue fraud claims. It also increases the pressure on companies to settle such claims despite their reasonable belief that they have complied with the law. Such settlements impose a substantial cost on pharmaceutical companies, which inevitably reduces the resources available for research and development of new drugs and other productive activities.

For these reasons, the Court should grant the petition for certiorari in order to resolve the conflict among the circuits and to make clear that FCA liability cannot be premised upon a reasonable interpretation of an ambiguous statute or regulation.

ARGUMENT

I. THE ISSUE RAISED BY THE PETITION IS EXCEEDINGLY IMPORTANT TO THE PHARMACEUTICAL INDUSTRY.

A. Pharmaceutical Companies Have Become A Primary Target Of FCA Suits, Many Of Which Have Resulted In Enormous Settlements.

In the last five years, pharmaceutical manufacturers have become a primary target of qui tam lawsuits under the FCA.[2]

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[2] *See generally* Jonathan K. Henderson & Quintin Cassady, *Drug Deals in 2006: Cutting Edge Legal and Regulatory Issues in the Pharmaceutical Industry*, 15 Annals Health. L. 107, 107 (2006) ("The pharmaceutical industry as a whole has come under increased regulatory scrutiny by federal

Many of these suits have been premised upon pharmaceutical companies' alleged failure to comply with the complex – and frequently ambiguous – statutes and regulations governing the Medicare and Medicaid programs. And these suits have sent shockwaves throughout the industry, as companies have found themselves suddenly and unexpectedly exposed to potentially devastating liabilities for practices that they reasonably believed were entirely lawful. See, *e.g.*, Scheineson & Klinger, *supra*, at 7 (noting that "the evolving use by the government of the fraud and abuse laws" has "force[d] settlements by drug and device manufacturers for conduct that was, in large part, viewed by FDA and other agencies as acceptable industry practice until DOJ and OIG began to redefine the regulatory landscape.").

The recent surge in FCA litigation against pharmaceutical manufacturers is of particular concern to the industry given the magnitude of the liability that attaches to violations of the FCA, which provides for treble damages and a fine of between $5,500 and $11,000 per false claim. The combination of legal uncertainty and the FCA's severe financial penalties has frequently led manufacturers to settle FCA claims rather than contest them. It is not uncommon for these settlements to run into the hundreds of millions of dollars. See Henderson & Cassady, *supra*, at 114-23 (summarizing recent FCA cases in which manufacturers paid sums ranging between

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and state governments as well as the plaintiff's bar over the past several years."); Marc J. Scheineson & Shannon Thyme Klinger, *Lessons from Expanded Government Enforcement Efforts Against Drug Companies*, 60 Food & Drug L.J. 1, 6 (2005) ("[T]he use of the FCA in pharmaceutical fraud and abuse actions has risen astronomically in the past five years."); Correy E. Stephenson, *Health Care Whistleblower Suits Are on the Rise*, Law. Wkly. USA, Nov. 21, 2005 (noting that health-care cases currently "dominate the qui tam landscape"); Peter Keisler, Assistant Att'y Gen., Civil Division, U.S. Dep't of Justice, Remarks to the Taxpayers Against Fraud Education Fund Conference for Relators' Counsel, Washington, D.C. (Oct. 14, 2004) (noting that, as of late 2004, there were approximately 100 whistleblower cases under seal involving allegations against over 200 drug manufacturers with respect to 500 different products).

$152 million and $560 million to settle FCA claims). In just nine of the largest FCA settlements by pharmaceutical companies in recent years, the companies involved paid an aggregate sum of nearly $3 billion. See The False Claims Act Legal Center, Top 20 Cases, *at* http://www.taf.org/top20.htm (last viewed Sept. 26, 2006). See also Stephenson, *supra* (noting that, of the $1.4 billion the United States recovered under the FCA in fiscal year 2005, $1.1 billion was associated with claims against health-care companies). In short, the amount of money the industry has at stake in these cases is staggering.

B. FCA Suits Against Pharmaceutical Companies Are Often Based On The Alleged Violation Of Ambiguous Regulations.

Many of the FCA claims that qui tam plaintiffs have brought against pharmaceutical companies in recent years have been based on the companies' alleged violation of ambiguous regulations. A full appreciation of the importance – and unfairness – of permitting FCA liability in such circumstances requires an understanding of the contractual and statutory contexts in which fraud claims against the pharmaceutical industry have arisen, and the ambiguities that have served as the basis for such claims.

Pharmaceutical manufacturers have numerous contractual relationships with government agencies, pursuant to which the manufacturers pay rebates, submit pricing information that establishes ceiling prices for certain categories of purchasers, or submit direct claims for payment. For example, under the terms of statutorily mandated contractual relationships, manufacturers report prices to the Health Resources and Services Administration that establish the ceiling price that may be charged to certain statutorily favored providers known as "340B" entities (*e.g.*, so-called "disproportionate share" hospitals and AIDS clinics). See 42 U.S.C. §

256b(a)(1).[3] Manufacturers likewise submit prices to the Department of Veterans Affairs ("VA") that establish the ceiling price that they generally must charge federal purchasers that acquire drugs off of the Federal Supply Schedule. See 38 U.S.C. § 8126.[4] Many manufacturers also contract directly to sell drugs to the VA, the Department of Defense, and other government agencies under the terms of standard government contacts.

The most significant contractual relationship between manufacturers and the government is the Medicaid Rebate Program. Under the terms of this program, manufacturers are obligated to pay the state Medicaid programs a quarterly rebate on each "covered drug," the magnitude of which is determined by the product of the "unit rebate amount" per unit of drug and the number of units reimbursed by each state during the relevant quarter. See 42 U.S.C. § 1396r-8(b)(1), (c)(1). Under the terms of the governing statute, manufacturers are obligated to enter into a contract – known as the standard Medicaid Drug Rebate Agreement ("MRA") – with the Centers for Medicare and Medicaid Services ("CMS"), which specifies the manufacturers' responsibilities and the government's remedies for breach. Collectively, manufacturers pay billions of dollars in rebates to the states every year. See, *e.g.*, GAO, Report to Cong. Requestors, *Medicaid Drug Re-*

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[3] Manufacturers' relationship with the government under the 340B Program is governed by a standard agreement with the Secretary of Health and Human Services. *See* Pharmaceutical Pricing Agreement § II(a) (Mar. 24, 2005) (on file with author) (requiring manufacturers "to charge covered entities a price for each unit of the drug that does not exceed an amount equal to the [average manufacturer price] for the covered outpatient drug" less a defined "rebate percentage").

[4] Manufacturers' relationship with the government under the VA Program is governed by a standard agreement with the Secretary of Veterans Affairs. *See* Master Agreement Between The Sec'y Of VA (Hereinafter Referred To As "The Sec'y") And The Mfr. Identified In Section VIII Of This Agreement (Hereinafter Referred To As "The Mfr.") § II-B1 (n.d.) (on file with author) ("Master Agreement") (specifying the "'annual Federal ceiling price'" manufacturers may charge the VA for covered drugs).

bate Program: Inadequate Oversight Raises Concerns about Rebates Paid to States 1 (Feb. 4, 2005) (reporting that manufacturers paid $5.6 billion in rebates to the states in 2002).

The rules governing the Medicaid Rebate Program, like most of the rules governing the Medicare and Medicaid programs, are extraordinarily complex. See, *e.g.*, *Rehabilitation Ass'n of Va., Inc.* v. *Kozlowski*, 42 F.3d 1444, 1450 (4th Cir. 1994) (observing that the Medicare and Medicaid statutes and regulations "are among the most completely impenetrable texts within human experience"). Pursuant to the rebate statute, for example, the unit rebate amount a manufacturer must pay each quarter to each state is generally based on the difference between two prices – the "average manufacturer price" ("AMP") and the "best price" – and manufacturers are required to report these prices to the federal government. The ambiguities in the statutory definitions of both AMP and "best price" are well-documented and have never been clarified by regulation: In the fifteen years since the inception of the program, CMS has proposed rules once (in 1995), but never finalized them. See Medicaid Program, Payment for Covered Outpatient Drugs Under Drug Rebate Agreements with Mfrs., 60 Fed. Reg. 48,442 (Sept. 19, 1995).

The lack of official guidance is a frequently cited problem for the administration of the rebate program. Indeed, last year the Government Accountability Office ("GAO") noted that "neither the rebate statute nor CMS had provided sufficiently detailed instructions on methods for calculating AMP." GAO, *supra*, at 13. GAO accordingly "recommended that [the Administrator of] CMS issue clear, updated guidance on manufacturer price determination methods" and the definitions of best price and AMP. *Id.* at 5. See also Office of the Inspector General, A-06-91-00092, *Medicaid Drug Rebates: The Health Care Financing Administration Needs to Provide Additional Guidance to Drug Manufacturers to Better Imple-*

ment the Program (Nov. 1992) (criticizing the lack of guidance regarding the definition of AMP).[5]

This lack of guidance, however, has not deterred qui tam plaintiffs from claiming that drug manufacturers have defrauded the government by incorrectly calculating their AMPs and "best prices." Such claims have led to many large FCA settlements.[6]

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[5] While CMS has never issued formal regulations, it has issued more than 80 program memoranda purporting to explain the provisions of the Medicaid Rebate statute. In many cases, such informal guidance has only exacerbated the problem. For example, in one release CMS attempted to clarify when manufacturers are required to include rebates offered to pharmacy benefit managers ("PBMs") in their AMP and "best price" calculations. *See* CMS, HHS, No. 28, Medicaid Drug Rebate Program Release, at 1 (1997). This release generated substantial confusion, so CMS issued another release purporting further to clarify its position. *See* CMS, HHS, No. 29, Medicaid Drug Rebate Program Release, at 1 (1997) ("The following item clarifies the information on the BP and AMP for PBMs provided in the Medicaid Drug Rebate Program Release No. 28."). When that release failed to resolve the issue, CMS issued yet another release acknowledging the confusion it had created and stating that it was "currently re-examining the issue and hope[d] to clarify [its] position in the near future." CMS, HHS, No. 30, Medicaid Drug Rebate Program Release, at 2 (1997). That release was issued in 1997, but CMS has yet to clarify its position.

[6] *See* Press Release, U.S. Dep't of Justice, Bayer Corp. & GlaxoSmithKline To Pay $344 Million To Resolve Allegations of Health Care Fraud Against State Programs (Apr. 16, 2003) (on file with author) (hereinafter Bayer/GlaxoSmithKline Press Release) (alleging that Bayer and GlaxoSmithKline failed to include the price of certain "private-label" sales in their best price reports for various drugs); Press Release, U.S. Dep't of Justice, Schering-Plough To Pay $345 Million To Resolve Criminal and Civil Liabilities for Illegal Marketing of Claritin (July 30, 2004) (on file with author) (alleging that Schering-Plough failed to account for certain discounts in its best price reports for Claritin); Press Release, U.S. Dep't of Justice, AstraZeneca Pharmaceuticals LP Pleads Guilty To Healthcare Crime; Company Agrees To Pay $355 Million To Settle Charges (June 20, 2003) (on file with author) (alleging that AstraZeneca failed to include certain price concessions in its best price reports for Zoladex); Press Release, U.S. Dep't of Justice, King Pharmaceuticals To Pay U.S. $124 Million For Medicaid Rebate Underpayments & Overcharging For Drug

For example, a number of settlements have grown out of the uncertainty over whether so-called "private-label" sales must be included in pharmaceutical companies' "best price" reports. "Best price" is defined by statute to be "the lowest price available from *the manufacturer* during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States," with specified exceptions. 42 U.S.C. § 1396r-8(c)(1)(C)(i) (emphasis added).

The definition of "best price" thus hinges on which company is deemed the "manufacturer" of a given drug. Unfortunately, the statute's use of the term "manufacturer" is ambiguous. Under the statutory definition, a "manufacturer" is, essentially, any entity that produces the drug or any entity that packages, labels, or distributes it.[7] Typically, both prongs of the definition identify the same entity as the "manufacturer" because a single entity produces, packages, labels, and distributes the drug.

This is not always the case, however. When one entity produces the drug and another packages, labels, or distributes it, there are two statutory "manufacturers" of the drug. This creates an anomaly, as the statutory definition of "best price" refers to the lowest price available from "the manufacturer"

Products (Nov. 1, 2005) (on file with author) (alleging that King failed to report accurately the AMP and best price for its Medicaid-reimbursed drugs); Press Release, U.S. Dep't of Justice, Drug Giant Pfizer & Two Subsidiaries To Pay $49 Million For Defrauding Drug Medicaid Rebate Program (Oct. 28, 2002) (on file with author) (alleging that Pfizer failed to include certain cash discounts in its best price report for Lipitor).

[7] "Manufacturer" is defined in full as "any entity which is engaged in—(A) the production, preparation, propagation, compounding, conversion, or processing of prescription drugs, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or (B) in the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products. Such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under state law." 42 U.S.C. § 1396r-8(k)(5).

and clearly contemplates that only one entity will have a rebate obligation.

Taking guidance from the Medicaid Drug Rebate Agreement CMS published in the Federal Register, pharmaceutical companies could reasonably resolve this well-documented statutory ambiguity by concluding that the "manufacturer" is the company that owns the National Drug Code ("NDC") number for the drug.[8] Accordingly, these companies would not include in their "best price" report the prices they offered for drugs sold pursuant to so-called "private-label" arrangements, *i.e.*, arrangements whereby the company agrees to produce the drugs under the customer's NDC number, and the customer distributes the drugs and in some cases repackages or relabels them. Quite reasonably, the companies following this interpretation would not consider themselves the "manufacturers" of the private-label drugs because they do not own the NDC numbers for those drugs.

Nonetheless, qui tam relators have filed suits alleging that these companies defrauded the government by not including private-label sales in their "best price" reports. In April 2003, for example, Bayer Corporation and GlaxoSmithKline agreed to pay a total of $344 million to settle an FCA case based on allegations of the companies' failure to include the prices of their private-label sales in their "best price" reports. See Bayer/GlaxoSmithKline Press Release.

Another issue arising out of the Medicaid Rebate Program is the scope of the "nominal price" exception to the definition of "best price." The rebate statute provides that "[t]he term 'best price' . . . shall not take into account prices that are merely nominal in amount." 42 U.S.C. § 1396r-8(c)(1)(C)(ii)(III). However, the statute does not define what amounts

[8] The Medicaid Drug Rebate Agreement specifies that the term "manufacturer" has the meaning set forth in the statute, "except, for purposes of this agreement, it shall also mean the entity holding legal title to or possession of the NDC number for the Covered Outpatient Drug." MRA § I(l), 56 Fed. Reg. 7049, 7051 (Feb. 21, 1991).

are "merely nominal"; nor does it define the entities that are eligible to receive such pricing. In the face of this statutory silence, the Secretary of Health and Human Services has interpreted the term "nominal price" in the Medicaid Drug Rebate Agreement as "any price less than 10% of the AMP in the same quarter for which the AMP is computed." MRA § I(s), 56 Fed. Reg. 7049, 7051 (Feb. 21, 1991); accord CMS, HHS, No. 14, Medicaid Drug Rebate Program Release, at 2 (1994). In accordance with the rebate agreement and subsequent CMS guidance, pharmaceutical companies could reasonably have decided not to include in their "best price" reports any prices discounted by more than 90 percent.

Yet again, however, FCA plaintiffs have converted such good-faith attempts to comply with a comprehensive regulatory scheme into allegations of fraud. In advocating for a narrower definition of the nominal price exception, these plaintiffs point to the legislative history of the rebate statute, which they argue shows that Congress intended to exclude those prices that "manufacturers offer to special purchasers, such as the sale of birth control pills for a penny a pack to Planned Parenthood." 136 Cong. Rec. S12954, S12962 (daily ed. Sept. 12, 1990). On the basis of this legislative history, the plaintiffs argue that sales with a commercial purpose do not come within the exception even if they would qualify as "nominal" under the Secretary's 10% interpretation. Referring to a dictionary definition, the plaintiffs also argue that the term "merely," as used in the rebate statute, should mean "without qualification." Thus, under their interpretation, prices that are "merely nominal in amount" are only those prices that are "nominal without qualification."

This argument has already prevailed in at least one FCA case. The United States District Court for the District of Nevada recently held that the phrase "'prices that are merely nominal in amount'" means "'all prices that are less than 10%

of the AMP, but without other qualifications'" or conditions.[9] *Nevada ex rel. Steinke* v. *Merck & Co.*, 432 F. Supp. 2d 1082, 1086 (D. Nev. 2006). Accordingly, the court refused to dismiss a state FCA action alleging that Merck & Co., Inc. had committed fraud by not including within its "best price" report the price of certain drugs it sold to hospitals at a 92% discount, even though Merck had quite reasonably interpreted the law to exclude those sales as falling within the nominal price exception.

The problem of ambiguous rules is of course not limited to the Medicaid Rebate Program. Another context in which pharmaceutical manufacturers have been charged with fraud under the FCA for allegedly violating ambiguous rules relates to the promotion of FDA approved drugs for additional therapies or uses that have not yet been approved by the FDA and are not included in the drug's label. Doctors are, in fact, allowed to use drugs "off-label" where there is scientific evidence to do so, and a large part of modern oncology therapy, for example, is done with off-label drugs.

While pharmaceutical manufacturers can provide relevant scientific evidence, they are not allowed to "promote" off-label uses of their drugs. This practice is known as "off-label" marketing. Creative FCA plaintiffs have argued that by promoting off-label uses of drugs in violation of the Food, Drug, and Cosmetic Act of 1938 ("FDCA"), manufacturers can "cause" the submission of false claims to the Medicare and Medicaid programs, which reimburse for some, but not all, off-label uses.

As the terminology suggests, a claim that a manufacturer has violated the FDCA depends on whether the manufacturer has "promoted" off-label uses of a drug. Not every statement by a manufacturer, however, is promotional, as the "FDA has

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[9] In so holding, the court failed to accord any deference to CMS's interpretation of the phrase "merely nominal in amount," as reflected in Section I(s) of the rebate agreement.

distinguished between those activities supported by manufacturers that are nonpromotional and otherwise independent from the substantive influence of the supporting manufacturer and those that are not," with only those activities in the latter category giving rise to a violation of the FDCA. Decision in *Washington Legal Found. v. Henney*, 65 Fed. Reg. 14,286, 14,287 (Mar. 16, 2000).

Unfortunately, the FDA's guidance as to which activities constitute impermissible "promotion" is notoriously inadequate. By way of example, almost ten years ago the agency published a Continuing Medical Education ("CME") guidance document in which it laid out an unwieldy twelve-pronged test for determining when a manufacturer's support of scientific and educational activities crosses the forbidden line into "promotion." See Final Guidance On Indus.-Supported Scientific Educ. Activity, 62 Fed. Reg. 64,074, 64,092-100 (Dec. 3, 1997). Many of the considerations outlined in the CME guidance are inherently vague.[10] Moreover, the factors listed are not exhaustive, and "[n]either the presence nor absence of any of the factors discussed in the CME guidance is necessarily dispositive in FDA's determination of whether it has adequate evidence to support a charge of misbranding." Letter from Margaret M. Dotzel, Assoc. Comm'r for Policy, FDA, to Daniel J. Popeo and Richard A. Samp 10 (Jan. 28, 2002), *available at* http://www.fda.gov/ohrms/dockets/dailys/02/Jan02/013002/01p-0250_pdn0001_01_vol2.pdf. Instead, the FDA has made clear that it will make decisions on a case-by-case basis, taking account of the totality of the circumstances. *Id.*

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[10] For example, the FDA considers whether: "the intent of the company and the provider is to produce an independent and promotional activity that is focused on educational content"; "the central theme is based on a single product marketed by the company or a competing product"; and "the title of the activity fairly and accurately represents the scope of the presentation."

Understandably frustrated by the lack of definitive guidance, manufacturers petitioned the FDA to issue additional guidance regarding manufacturer sponsorship of scientific and educational activities, but the FDA refused to do so. See *id.* (denying the petition and stating that "FDA has no current plan to expand or alter its CME guidance"). Manufacturers thus continue to face an unacceptable level of uncertainty as to which activities will be deemed illegal. As one court observed, "[a]fter six years' worth of briefs, motions, opinions, Congressional acts, and more opinions, the issue remains 100% unresolved, and the country's drug manufacturers are still without clear guidance as to their permissible conduct." *Washington Legal Found.* v. *Henney*, 128 F. Supp. 2d 11, 15 (D.D.C 2000). Indeed, the court viewed the argument that the FDA's off-label regulations are sufficiently clear as "a farce."[11] *Id.*

Not surprisingly, FCA plaintiffs have found ways to take advantage of the ambiguities in the regulations governing manufacturers' dissemination of information about off-label uses. These plaintiffs have brought suits alleging that manufacturers illegally promoted off-label uses of their drugs and

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[11] The FDA has similarly failed to issue adequate guidance relating to other aspects of the distinction between "promotion" and lawful dissemination of information. For example, the FDA generally permits companies to "disseminate information on unapproved uses in response to unsolicited requests for scientific information from health care professionals." Citizen Petition Regarding the FDA's Policy on Promotion of Unapproved Drugs and Devices, 59 Fed. Reg. 59,820, 58,823 (Nov. 18, 1994). The FDA, however, has failed to issue regulations addressing widespread questions in the industry as to the scope of this "unsolicited request" policy, such as which activities will be deemed a disqualifying "solicitation" of a request and whether the company's response must come from representatives of its medical department (as opposed to other personnel, such as sales representatives). In 1997, the FDA stated that it would issue a guidance document specifically addressing "Solicited and Unsolicited Requests for Information," Prescription Drug Advertising & Promotional Labeling; Development & Use of FDA Guidance Documents, 62 Fed. Reg. 14,912, 14,916 (Mar. 28, 1997), but it has yet to do so.

that their promotional activities caused doctors to submit false reimbursement claims to Medicare and Medicaid. In the absence of a clear rule that a reasonable interpretation of ambiguous rules cannot give rise to FCA liability, these plaintiffs have been able to force large FCA settlements notwithstanding the deep ambiguity of the off-label regulatory environment.[12]

There are many other examples of ambiguities in the federal health-care programs that have produced, or may yet produce, allegations of fraud under the FCA. As long as there is disagreement among the circuits as to whether FCA liability can attach to claims submitted to the government in accordance with an objectively reasonable interpretation of an ambiguous regulation, would-be FCA plaintiffs have every incentive to search out and exploit these ambiguities by filing FCA actions and leveraging uncertain legal exposure into settlements. There can thus be no doubt that the issue presented by this petition is a live question that has vitally important implications for the pharmaceutical industry.[13]

C. There Are Other Remedies Available To Ensure Compliance With Regulatory Requirements.

A rule limiting the ability of qui tam plaintiffs to pursue lucrative fraud claims for alleged violations of ambiguous regulations would not deprive the government of legitimate remedies. The government has at its disposal numerous tools to clarify ambiguous regulations. Indeed, the rule advocated herein would have the salutary effect of encouraging government agencies to utilize their notice and comment rulemaking procedures to clarify statutory and regulatory ambiguities.

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[12] *See, e.g.*, Press Release, U.S. Dep't of Justice, Warner-Lambert To Pay $430 Million To Resolve Criminal & Civil Health Care Liability Relating To Off-Label Promotion (May 13, 2004) (on file with author).

[13] The issue is also undoubtedly important to other sectors of the economy, such as defense contracting, that involve pervasive dealings with the government under complicated regulatory schemes.

In addition, the government has the means to require corrective action by pharmaceutical companies under a variety of circumstances. Most critically, when disputes arise over the meaning of regulations governing contractual relationships with the government, the government can invoke the remedial provisions of the contract at issue. Disputes over AMP and "best price," for example, all arise in the context of a contract – the Medicaid Drug Rebate Agreement – under which the government has a variety of remedial options. Perhaps most significantly, the government can terminate the agreement if it believes the manufacturer has violated the contract or there is other good cause. MRA § VIII(c), 56 Fed. Reg. at 7053. This is a significant stick for the government, for if an agreement is terminated, the manufacturer is prohibited from entering into another rebate agreement in the next quarter, in which case the manufacturer's drugs will not be eligible for Medicaid reimbursement. *Id.* § VIII(d). Moreover, if the government believes that a manufacturer has reported false information, it can invoke the penalty provisions of the agreement, which authorize the Secretary to impose a civil penalty of up to $100,000 for each item of false information. *Id.* § IV.

Similar contractual provisions apply to pharmaceutical manufacturers' reporting of prices to the Health Resources and Services Administration under the standard Pharmaceutical Pricing Agreement ("PPA") that governs manufacturers' relationship with the government in the 340B Program. The government can pursue a variety of remedies for perceived noncompliance or fraud. PPA § IV(c) (Mar. 24, 2005). It can "initiate the informal dispute resolution process," "require the Manufacturer to reimburse the entity for discounts withheld," or "terminate the Agreement." *Id.*

Likewise, when a pharmaceutical manufacturer submits claims to the government pursuant to a standard procurement contract, the government can pursue standard contractual remedies that apply generally to government contracts. Un-

der the Master Agreement governing pharmaceutical companies' provision of drugs to the VA, for example, if the government believes that a manufacturer is violating the terms of the contract, it can invoke the provisions of the Contract Disputes Act. Master Agreement § V(B). Pursuant to these provisions, the "contracting officer" for the government is "authorized . . . to decide or resolve all claims arising under or relating to a contract." 48 C.F.R. § 33.210. The contracting officer's decision is "final unless the Contractor appeals or files a suit as provided in the Act." *Id.* § 52.233-1(f). Thus, the government is able to resolve contract disputes in the first instance according to its preferred interpretation of the rules or regulations at issue. The onus is then on the contractor to challenge the government's decision through an internal appeals process or by filing suit in the Court of Federal Claims.

This case is thus *not* about whether an FCA defendant that acts on the basis of a reasonable interpretation of a regulation should be immune from all remedial measures if the government's contrary interpretation of the regulation is ultimately deemed correct. Rather, this case is *only* about whether an individual or entity should be held liable *for fraud* for submitting claims to the government in accordance with a reasonable interpretation of an ambiguous regulation. This Court should grant the petition to make clear that such conduct does not constitute fraud and therefore does not give rise to liability under the FCA.

II. THE DECISION BELOW IS WRONG, CREATES UNCERTAINTY, AND INCREASES THE INCENTIVE TO SETTLE MERITLESS FCA SUITS.

The decision below is plainly wrong. As petitioner has explained, allowing FCA liability to be premised upon claims submitted to the government in accordance with an objectively reasonable interpretation of ambiguous regulations is inconsistent with due process, the rule of lenity, the principle that ambiguous provisions should be construed against the drafter, and the federal courts' uniform interpretation of the

criminal False Claims Act. See Petition for Certiorari ("Pet.") 16-27. At bottom, these arguments all sound in a common theme: it is fundamentally unfair to hold someone liable *for fraud* when the sole basis for such liability is that he acted pursuant to a reasonable interpretation of an ambiguous regulation. Cf. *Walker Process Equip., Inc.* v. *Food Mach. & Chem. Corp.*, 382 U.S. 172, 176-77 (1965) (recognizing in another context that "an honest mistake" provides a "complete defense" to a claim of fraud); *United States* v. *Southland Mgmt. Corp.*, 326 F.3d 669, 684 (5th Cir. 2003) ("'Where there are legitimate grounds for disagreement over the scope of a contractual or regulatory provision, and the claimant's actions are in good faith, the claimant cannot be said to have knowingly presented a false claim.'") (citation omitted).

Furthermore, the decision below creates an intolerable level of uncertainty. Those who submit claims for payment to the federal government pursuant to complex regulatory schemes must frequently make choices about how to comply with ambiguous provisions. The risk that each of these choices could give rise to treble damages plus substantial per-claim penalties could severely impair the efficiency of an industry. See Scheineson & Klinger, *supra*, at 11 (noting that it is "impossible to predict with any certainty which of today's accepted pharmaceutical industry practices may be challenged . . . as violative of fraud and abuse laws."). At very least, it substantially increases the cost of doing business with the government. See Henderson & Cassady, *supra*, at 107-08 (noting that FCA litigation "has caused confusion and uncertainty between pharmaceutical manufacturers and the providers and suppliers with whom they conduct federal health care program business").

The conflict that petitioner has demonstrated among the courts of appeals, see Pet. 9-16, needlessly exacerbates the uncertainty companies face when deciding whether to litigate or settle FCA actions premised upon the alleged violation of ambiguous regulations. Manufacturers sued in circuits that

have not addressed the issue must attempt to divine the applicable legal rule in the face of conflicting decisions from other circuits. In the absence of a clear and uniform rule, the obvious incentive is to settle such cases in order to gain certainty and avoid exposure to the FCA's draconian financial penalties. See, *e.g.*, Scheineson & Klinger, *supra*, at 6 (noting that "the FCA provides a substantial economic incentive not only for employees, competitors, and others to report allegedly fraudulent activities by pharmaceutical companies to DOJ, but also for DOJ to pursue such actions in hopes of forcing manufacturers to resolve matters rather than face the catastrophic economic exposure brought by an adverse ruling at trial").

Thus, if the conflict is allowed to persist, companies will continue to face pressure to pay huge amounts to settle FCA actions despite their insistence that they have done nothing illegal or fraudulent. See, *e.g.*, *SmithKline Whistleblowers Get $42.3 Million*, Pa. L. Wkly., Apr. 20, 1998, at 1 (noting that, even after paying $325 million, SmithKline "denied the allegations, saying the violations were unintentional and the result of ambiguities in regulations and guidelines"). Moreover, given the substantial sums involved in many of these settlements, would-be relators will continue to have a substantial incentive to exploit ambiguities in the hopes of forcing a lucrative settlement. See Henderson & Cassady, *supra*, at 116, 119, 121, 123 (reporting that the relators' recoveries in four major settlements were $31.6 million, $24.64 million, $47.5 million, and $34.2 million).

The overwhelming incentive to settle these cases also provides a compelling reason for the Court to grant the petition in this case. Settlements in this area have short-circuited the judicial process, preventing courts from ruling on the merits of the claims and potential defenses. Consequently, the question presented by the petition is (to borrow a phrase from another context) capable of repetition yet evading review. The decision below is exceptional in that the court not only con-

fronted the question, but also resolved it in a way that squarely presents it for this Court's review. See Petr's App. 12a (recognizing that "the regulatory language . . . was ambiguous," but nonetheless allowing plaintiff's FCA action to proceed). The Court should thus take this opportunity to resolve the issue and thereby provide a measure of certainty to companies faced with FCA claims.

Finally, the significant sums paid by pharmaceutical companies to settle these dubious FCA actions, as well as the risk that qui tam relators will find more ambiguities to exploit, are a significant cost of doing business. As such, they inevitably diminish the resources available for productive activities such as the research and development of new drugs. Pharmaceutical manufacturers pay a significant amount of money to participate in and comply with government programs. They should not be required to pay a further premium to finance the settlement of extortionate lawsuits that seek to convert their reasonable attempts to comply with ambiguous regulations into fraud.

For each of these reasons, the Court's review is urgently required to resolve the conflict among the circuits and to make clear that a reasonable interpretation of an ambiguous statute or regulation cannot give rise to liability for fraud under the FCA.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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